UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,536	01/23/2002	Sukanta Dutta	1997.341 US D1	9200

31846 7590 06/10/2005

INTERVET U.S.
PATENT DEPARTMENT
PO BOX 318
MILLSBORO, DE 19966-0318

EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,536	DUTTA ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,34 and 36* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. Acknowledgment and entry of the Amendment submitted on 2/14/05 is made. Claims 30, 34 and 36 are currently pending.

Election/Restrictions

2. Newly submitted claim 36 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claim 36 is drawn to a vaccine comprising *a purified protein antigen*, never before presented. The claims under examination are drawn to a whole cell vaccine and a method of protection using said whole vaccine. If this claim were originally presented it would have been restricted from the present claims. A whole cell bacterium and an isolated protein antigen are biologically, chemically and structurally different products and therefore patentably distinct and independent inventions. A literature search for an isolated protein would not necessarily reveal art towards the bacterium from which it was derived and vice versa. Protein vaccines and whole cell vaccines are very different.

Group I, claims 30 and 34 drawn to whole cell vaccines, class 424, subclass 234.1

Group II, claim 36, drawn to a vaccine comprising a purified antigen, class 530, subclass 530/350.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Applicants are only entitled to examination of one invention per application. Accordingly, claim 36 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 30 and 34 are currently under examination.

Claim Rejections - 35 USC § 112-Scope of Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 30 and 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "A vaccine comprising an immunologically effective amount of a *E. risticii* 90-12 strain and a pharmaceutically acceptable carrier or diluent" and "a method of protecting a mammal against Potomac Horse Fever comprising administering an effective amount of the vaccine", does not reasonably provide enablement for "A vaccine comprising an immunologically effective amount of a killed *E. risticii* strain having an 85 kilodalton gene and a pharmaceutically acceptable carrier or diluent". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are broadly drawn to 'A vaccine comprising *any* isolated strain of *E. risticii* having an 85kDa gene'. The instant specification only describes *E.risticii* strain 90-12 (isolated in 1990) and *E.risticii* strain 25D (isolated in 1984). The specification provides no description of any other *E.risticii* strains. There is no teaching

of any other bacterial organism which has an 85-kDa gene other than *E. risticii* strain 90-12. The specification does not provide enablement for any strains, other than the 90-12 strain, which comprise this gene. The prior art teaches inactivated strains *E.risticii* strain 90-12 (isolated in 1990) and *E.risticii* strain 25D (isolated in 1984 and which does not contain an 85-Kda gene) were well known as whole cell vaccines. However, there is no description of any other strains in the prior art or instant specification which have an 85-kDa gene, much less which can be successfully used as a vaccine. Additionally, the word "killed" (e.g., killed vaccine) cannot be found in the instant specification. The prior art and specification teach that the live vaccines have proven effective. The specification does not provide written support for the word "killed", nor does it teach "inactivated". See Written Description rejection below. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." It would take one of skill in the art undue experimentation to discover a strain of *E. risticii* bacteria which has an 85-kda gene and can successfully protect

mammals against Potomac Horse Fever. The function of the 85-kDa gene is also not taught making the search for such a strain even more difficult. The specification does not enable the instant claims.

The Dissertation by inventor Biswajit Biswas of 1996 (Molec.Basis of Antigenic Variation of Strain Specific Surface Antigen Gene of *Ehrlichia risticii* and Development of a Multiplex PCR Assay for Differentiation of Strains, University of Maryland, College Park) teaches that the 90-12 strain was isolated from a vaccinated horse strain and was found to contain a 85kDa antigen, while the 25-D strain (isolated in 1984) contained a 50kDa antigen. This reference further emphasizes the point that all 90-12 strains were found to contain this antigen.

Applicants have stated under their response to the former 112, second paragraph rejections that they have discovered a variance in the 90-12 strain which causes it to be immunogenic. Applicants seem to be implying that they have discovered variance among the 90-12 strains themselves, yet the specification only teaches the 90-12 strains and the prior art and specification teach that all 90-12 strains contain this 85kDa antigen. All experiments described in the instant specification used the well-known 90-12 strains which were isolated around 1990. The specification teaches that all 90-12 strains have an 85-kDa gene which appears to make them more immunogenic than the 25-D strains. However, the 90-12 strains were well known in the prior art at the time the invention was made. Accordingly, the discovery of an inherent property of a known product (a 90-12 *E. risticii* bacteria) does not impart novelty. The specification is not enabled for any *E. risticii* bacteria strain possessing an 85-kDa gene because they

have only taught its presence in the 90-12 strain. It would take undue experimentation to discover a new strain possessing an 85-kDa gene. It is noted on page 12 of Applicants' Response under part D, that they recite "Applicant is claiming the immunogenic characteristics of the 85 kilodalton gene of an *E.risticii* strain". This is not a accurate. Claim 30 is claiming the well-known 90-12 strain which inherently possess the 85 kDa gene. As stated above, the discovery of an inherent property of a known product (a 90-12 *E. risticii* bacteria) does not impart novelty. Applicants also state that the parent application, US Pat. No. 6,375,954 does not have an 85 kD gene as claimed by Applicant and appears to implying that the strains in the parent case are different from those in the present case. It is noted that this application is a Divisional from the parent application. Accordingly, the specification/disclosures are identical. If Applicant has discovered something new between the filing of the parent application and this application, then a CIP or new application would need to be filed and Applicants would not be entitled to the earlier filing date. A review of the parent application disclosure appears to be identical to the instant disclosure so it is unclear what Applicants intend when they state that "the parent application, US Pat. No. 6,375,954 does not have an 85 kD gene as claimed". Clarification is requested in this matter.

Claim Rejections - 35 USC § 112-New Matter

5. Claims 30 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The word "killed" (e.g., killed vaccine) cannot be found in the instant specification or the originally filed claims. The Examiner pointed this out in the previous Office Action mailed on 10/22/04; however Applicants failed to address this point. Applicants must point to support for this limitation by page and line number or it must be removed from the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vemulapalli et al (J. Clin. Microbiol. Nov. 1995. 33(11): 2987-2993) in view of Dutta (US 4,759,927).

Vemulapalli et al teach isolated strains of *E.risticii* 90-12 and 25-D. The 90-12 strains inherently possess an 85kDa gene. Vemulapalli et al also teach that strain variation in *E.risticii* is not unexpected because there are several different strains clearly established in other rickettsial organisms. Biological diversity of nine clinical isolates of *E.risticii* was reported in 1994. See page 2992, last paragraph, column 1. The term "vaccine" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The reference describes mouse protection experiments which comprise administering an effective amount of strains *E.risticii* 90-12 and 25-D to mice and then challenging them with the strains. Administration of strain *E.risticii* 90-12 was shown to induce immunity to both wild-type *E.risticii* 90-12 and *E.risticii* 25-D.

However, Vemulapalli et al do not specifically recite that the strains could be killed.

Dutta et al teach a vaccine against Potomac horse fever which comprises inactivated strains of *E.risticii.* The vaccine is chemically inactivated (killed). The vaccine was delivered to horse in a pharmaceutically acceptable carrier. The horses were subsequently challenged with *E.risticii.* The vaccine was shown to confer a large measure of protection. In many cases, no symptoms of Potomac horse fever were observed. See column 2, lines 38-67.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made that the 90-12 strain of Vemulapalli could have been chemically inactivated (killed) because Dutta teaches inactivating strains of *E.risticii* prior to administering them to a mammal. One of ordinary skill in the art would have been motivated to use the vaccine as a killed vaccine to avoid infecting the mammals with the infective agent against which protection is taught. Killing whole cell bacterial vaccines prior to administration to a host was well-known and a common practice in the prior art at the time the invention was made as evidenced by the Dutta reference. As

noted in the Written Description rejection above, the instant specification fails to recite the limitation "killed". If this were removed from the claims then Vemulapalli would be a 102(b) reference.

8. Applicant's amendment/submission necessitated the new ground(s) of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 6/8/05

Jennifer Graser
Primary Examiner
Art Unit 1645